

2007 FEB 23 AM 7:07

201-16554Y

# I U C L I D

## Data Set

**Existing Chemical** : ID: 131-11-3  
**CAS No.** : 131-11-3  
**EINECS Name** : dimethyl phthalate  
**EC No.** : 205-011-6  
**TSCA Name** : 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Molecular Formula** : C10H10O4

**Producer related part**  
**Company** : ExxonMobil Biomedical Sciences Inc.  
**Creation date** : 16.10.2000

**Substance related part**  
**Company** : ExxonMobil Biomedical Sciences Inc.  
**Creation date** : 16.10.2000

**Status** :  
**Memo** : ACC Phthalate Ester Panel HPV Testing Group

**Printing date** : 13.12.2006  
**Revision date** :  
**Date of last update** : 13.12.2006

**Number of pages** : 33

**Chapter (profile)** : Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10  
**Reliability (profile)** : Reliability: without reliability, 1, 2, 3, 4  
**Flags (profile)** : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),  
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

# 1. General Information

Id 131-11-3

Date 13.12.2006

## 1.0.1 APPLICANT AND COMPANY INFORMATION

Type : lead organisation  
Name : ACC Phthalate Esters Panel HPV Testing Group  
Contact person : Dr. Marian Stanley  
Date :  
Street : 1300 Wilson Blvd.  
Town : 22209 Arlington, VA  
Country : United States  
Phone : (703) 741-5623  
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Telex :  
Cedex :  
Email :  
Homepage :

Remark : The American Chemistry Council Phthalate Esters Panel includes the following member companies:

BASF Corporation  
CONDEA Vista Company  
Eastman Chemical Company  
ExxonMobil Chemical Company  
Ferro Corporation  
ICI Americas / Uniqema  
Sunoco Chemicals  
Teknor Apex Company

02.11.2001

## 1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

## 1.0.3 IDENTITY OF RECIPIENTS

## 1.0.4 DETAILS ON CATEGORY/TEMPLATE

Comment : This chemical is part of the Low Molecular Weight Phthalate Esters subcategory. The subcategory includes the following two CAS numbers: 131-11-3 and 84-66-2

Remark : This chemical is part of the Low Molecular Weight Phthalate Esters subcategory. The subcategory includes the following two CAS numbers and names:  
131-11-3 1,2-Benzenedicarboxylic acid, dimethyl ester (DMP)  
84-66-2 1,2-Benzenedicarboxylic acid, diethyl ester (DEP)

The phthalate esters comprise a family of chemicals synthesized by esterifying phthalic anhydride with various alcohols in the presence of an acid catalyst. Phthalate esters are all 1,2-benzenedicarboxylic acids with side chain ester groups ranging from C1 to approximately C13. The structural characteristics of the ester side chains affect both the physical/chemical and biological properties of phthalate esters.

Phthalate esters are generally clear to yellow, oily liquids with high boiling ranges (>250°C) and low vapor pressures; properties which contribute to

their high physical stability. They are readily soluble in most organic solvents and miscible with alcohol, ether and most oils. The aqueous solubility of phthalate esters is inversely related to their molecular weights. Lower molecular weight phthalates exhibit slight to moderate water solubility, whereas, higher molecular weight phthalates exhibit very low solubility.

The phthalate esters were subdivided into three subcategories based on their physicochemical and toxicological properties. The phthalate esters in this subcategory, Low molecular weight phthalates, are produced from alcohols with straight-chain carbon backbones of  $<C_3$ . The U.S. HPV chemicals, dimethyl (DMP) and diethyl (DEP) phthalate, are included in this subcategory. Low molecular weight phthalates are commonly used as solvents or in cellulose acetate polymers rather than as plasticizers for PVC. Their relatively higher volatility and water solubility give them properties different than other phthalate esters in this category, some of which translate to different biological properties. In particular, these phthalates have greater aqueous solubility, resulting in a potential to cause acute toxic effects in aquatic organisms.

14.04.2006

**1.1.0 SUBSTANCE IDENTIFICATION****1.1.1 GENERAL SUBSTANCE INFORMATION**

Purity type	:	
Substance type	:	organic
Physical status	:	liquid
Purity	:	
Colour	:	
Odour	:	

02.11.2001

**1.1.2 SPECTRA****1.2 SYNONYMS AND TRADENAMES****1.3 IMPURITIES****1.4 ADDITIVES****1.5 TOTAL QUANTITY****1.6.1 LABELLING****1.6.2 CLASSIFICATION**

## 1. General Information

Id 131-11-3  
Date 13.12.2006

### 1.6.3 PACKAGING

### 1.7 USE PATTERN

Type of use : industrial  
Category : Basic industry: basic chemicals

Remark : Low molecular weight phthalates are commonly used as solvents or in cellulose acetate polymers rather than as plasticizers for PVC.  
02.11.2001

### 1.7.1 DETAILED USE PATTERN

### 1.7.2 METHODS OF MANUFACTURE

## 1.8 REGULATORY MEASURES

### 1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

### 1.8.2 ACCEPTABLE RESIDUES LEVELS

### 1.8.3 WATER POLLUTION

### 1.8.4 MAJOR ACCIDENT HAZARDS

### 1.8.5 AIR POLLUTION

### 1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

### 1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

### 1.9.2 COMPONENTS

### 1.10 SOURCE OF EXPOSURE

### 1.11 ADDITIONAL REMARKS

**1.12 LAST LITERATURE SEARCH**

**1.13 REVIEWS**

## 2. Physico-Chemical Data

Id 131-11-3

Date 13.12.2006

### 2.1 MELTING POINT

**Value** : 5.5 °C  
**Sublimation** :  
**Method** : other: no data  
**Year** :  
**GLP** :  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Remark** : Data are from a peer reviewed literature review of data from a variety of sources including manufacturer's data or handbook values.

**Test substance** : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Reliability** : (2) valid with restrictions  
This robust summary is assigned a reliability of 2 because there is limited information on how the data were developed.

**Flag** : Critical study for SIDS endpoint  
14.04.2006 (12)

**Value** : -23 °C  
**Decomposition** : no, at °C  
**Sublimation** : no  
**Method** : other: calculation  
**Year** :  
**GLP** :  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Method** : Melting point calculation by MPBPWIN ver. 1.41 using calculation methods of Joback and Gold and Ogle.

**Remark** : EPI Suite™ is used and advocated by the US EPA for chemical property estimation. However, the melting point calculation in EPI Suite™ gives erroneously high results for the phthalate esters.

**Test substance** : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Reliability** : (3) invalid  
14.04.2006 (4)

### 2.2 BOILING POINT

**Value** : 249 °C at 1013 hPa  
**Decomposition** :  
**Method** : other: calculation  
**Year** :  
**GLP** :  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Method** : Boiling point calculation by MPBPWIN ver. 1.41 using calculation method of Stein and Brown.

**Remark** : EPI Suite™ is used and advocated by the US EPA for chemical property estimation.

**Test substance** : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Reliability** : (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are calculated.

**Flag** : Critical study for SIDS endpoint  
14.04.2006 (4)

## 2.3 DENSITY

## 2.3.1 GRANULOMETRY

## 2.4 VAPOUR PRESSURE

Value : .00263 hPa at 25 °C  
 Decomposition : no  
 Method : other (calculated)  
 Year :  
 GLP :  
 Test substance : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

Method : Measured data collected and tabulated, calculated data also considered in determining recommended values.

Remark : Physicochemical data for selected commercial phthalate esters from various sources including the public literature, manufacturing specifications, and handbook values were evaluated by an industry peer review process. Valid values were identified and presented in a phthalate ester environmental fate, peer reviewed publication. These data, including the values for vapour pressure, represent the definitive and currently accepted physicochemical database for selected phthalate esters including dimethyl phthalate.

Quantitative structure-property relationships, significant at the 99.9% level, were developed using the relevant phthalate ester data to estimate solubility in water, air, and octanol, where V = the Le Bas molar volume (cm<sup>3</sup> mol<sup>-1</sup>). The Le Bas molar volume used for dimethyl phthalate ester was 206.4 cm<sup>3</sup> mol<sup>-1</sup>.

Log CS(WL) = -0.012V + 5.8, n = 35 (solubility in water)  
 r<sup>2</sup> = 0.98, SE = 0.39

Log CS(AL) = -0.013V - 1.3, n = 15 (solubility in air)  
 r<sup>2</sup> = 0.87, SE = 0.33

Log CS(OL) = -0.016V + 3.4, n = 68 (solubility in octanol)  
 r<sup>2</sup> = 0.19, SE = 0.41

It was recommended by the authors that the above regressions be used for predicting the three solubilities for phthalate esters with alkyl chain lengths from 1 to 13 carbons.

Test substance : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
 Reliability : (2) valid with restrictions  
 The value was calculated based on the QSPR (quantitative structure-property relationship) three-solubility model. This robust summary has a reliability rating of 2 because the data are calculated and not measured.

Flag : Critical study for SIDS endpoint  
 14.04.2006

(1)

Value : .0062 hPa at 25 °C  
 Decomposition : no  
 Method : other (calculated)  
 Year :  
 GLP :  
 Test substance : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

## 2. Physico-Chemical Data

Id 131-11-3

Date 13.12.2006

**Method** : Vapor pressure calculation by MPBPWIN ver. 1.41 using calculation method of Grain.  
**Remark** : EPI Suite™ is used and advocated by the US EPA for chemical property estimation.  
**Test substance** : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Reliability** : (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are calculated.

14.04.2006

(4)

### 2.5 PARTITION COEFFICIENT

**Partition coefficient** : octanol-water  
**Log pow** : 1.61 at 25 °C  
**pH value** :  
**Method** : other (calculated)  
**Year** :  
**GLP** :  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Method** : Measured data collected and tabulated, calculated data also considered in determining recommended values.

**Remark** : Physicochemical data for selected commercial phthalate esters from various sources including the public literature, manufacturing specifications, and handbook values were evaluated by an industry peer review process. Valid values were identified and presented in a phthalate ester environmental fate, peer reviewed publication. These data, including the values for partition coefficient, represent the definitive and currently accepted physicochemical database for selected phthalate esters including dimethyl phthalate.

Quantitative structure-property relationships, significant at the 99.9% level, were developed using the relevant phthalate ester data to estimate solubility in water, air, and octanol, where V = the Le Bas molar volume (cm<sup>3</sup> mol<sup>-1</sup>). The Le Bas molar volume used for dimethyl phthalate ester was 206.4 cm<sup>3</sup> mol<sup>-1</sup>.

Log CS(WL) = -0.012V + 5.8, n = 35 (solubility in water)  
r<sup>2</sup> = 0.98, SE = 0.39

Log CS(AL) = -0.013V - 1.3, n = 15 (solubility in air)  
r<sup>2</sup> = 0.87, SE = 0.33

Log CS(OL) = -0.016V + 3.4, n = 68 (solubility in octanol)  
r<sup>2</sup> = 0.19, SE = 0.41

It was recommended by the authors that the above regressions be used for predicting the three solubilities for phthalate esters with alkyl chain lengths from 1 to 13 carbons.

**Test substance** : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Reliability** : (2) valid with restrictions

The value was calculated based on the QSPR (quantitative structure-property relationship) three-solubility model. This robust summary has a reliability rating of 2 because the data are calculated and not measured.

**Flag** : Critical study for SIDS endpoint

14.04.2006

(1)

**Partition coefficient** : octanol-water  
**Log pow** : 1.66 at 25 °C  
**pH value** :



## 2. Physico-Chemical Data

Id 131-11-3

Date 13.12.2006

Method : other (calculated)  
Year :  
GLP :  
Test substance : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

Method : Partition coefficient by LOGKOWWIN ver. 1.67 using an atom/fragment calculation method of Meylan and Howard.

Remark : EPI Suite™ is used and advocated by the US EPA for chemical property estimation.

Test substance : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

Reliability : (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are calculated.

14.04.2006

(4)

### 2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in : Water  
Value : 5220 mg/l at 25 °C  
pH value :  
concentration : at °C  
Temperature effects :  
Examine different pol. :  
pKa : at 25 °C  
Description :  
Stable :  
Deg. product :  
Method : other: calculated  
Year :  
GLP :  
Test substance : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

Method : Measured data collected and tabulated, calculated data also considered in determining recommended values.

Remark : Physicochemical data for selected commercial phthalate esters from various sources including the public literature, manufacturing specifications, and handbook values were evaluated by an industry peer review process. Valid values were identified and presented in a phthalate ester environmental fate, peer reviewed publication. These data, including the values for water solubility, represent the definitive and currently accepted physicochemical database for selected phthalate esters including dimethyl phthalate.

Quantitative structure-property relationships, significant at the 99.9% level, were developed using the relevant phthalate ester data to estimate solubility in water, air, and octanol, where  $V$  = the Le Bas molar volume ( $\text{cm}^3 \text{mol}^{-1}$ ). The Le Bas molar volume used for dimethyl phthalate ester was  $206.4 \text{ cm}^3 \text{mol}^{-1}$ .

$\text{Log CS(WL)} = -0.012V + 5.8$ ,  $n = 35$  (solubility in water)  
 $r^2 = 0.98$ ,  $\text{SE} = 0.39$

$\text{Log CS(AL)} = -0.013V - 1.3$ ,  $n = 15$  (solubility in air)  
 $r^2 = 0.87$ ,  $\text{SE} = 0.33$

$\text{Log CS(OL)} = -0.016V + 3.4$ ,  $n = 68$  (solubility in octanol)  
 $r^2 = 0.19$ ,  $\text{SE} = 0.41$

It was recommended by the authors that the above regressions be used for predicting the three solubilities for phthalate esters with alkyl chain lengths

## 2. Physico-Chemical Data

Id 131-11-3  
Date 13.12.2006

Test substance : from 1 to 13 carbons.  
Reliability : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
: (2) valid with restrictions  
The value was calculated based on the QSPR (quantitative structure-property relationship) three-solubility model. This robust summary has a reliability rating of 2 because the data are calculated and not measured.

Flag : Critical study for SIDS endpoint  
14.04.2006 (1)

Solubility in : Water  
Value : 2014 mg/l at 25 °C  
pH value :  
concentration : at °C  
Temperature effects :  
Examine different pol. :  
pKa : at 25 °C  
Description :  
Stable :  
Deg. product :  
Method : other: calculated  
Year :  
GLP :  
Test substance : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

Method : Water solubility calculated using WSKOWN ver 1.41 based on Kow correlation method of Meylan and Howard. Kow used in calculation was 1.6.

Remark : EPI Suite™ is used and advocated by the US EPA for chemical property estimation.

Test substance : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
Reliability : (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are calculated.

14.04.2006 (4)

### 2.6.2 SURFACE TENSION

### 2.7 FLASH POINT

### 2.8 AUTO FLAMMABILITY

### 2.9 FLAMMABILITY

### 2.10 EXPLOSIVE PROPERTIES

### 2.11 OXIDIZING PROPERTIES

### 2.12 DISSOCIATION CONSTANT

## 2. Physico-Chemical Data

Id 131-11-3  
Date 13.12.2006

### 2.13 VISCOSITY

### 2.14 ADDITIONAL REMARKS

### 3. Environmental Fate and Pathways

Id 131-11-3

Date 13.12.2006

#### 3.1.1 PHOTODEGRADATION

Type : air  
Light source : Sun light  
Light spectrum : nm  
Relative intensity : 1 based on intensity of sunlight  
Conc. of substance : at 25 °C  
INDIRECT PHOTOLYSIS  
Sensitizer : OH  
Conc. of sensitizer : 1500000 molecule/cm<sup>3</sup>  
Rate constant : .0000000000005738 cm<sup>3</sup>/(molecule\*sec)  
Degradation : 50 % after 18.6 day(s)  
Deg. product : not measured  
Method :  
Year :  
GLP :  
Test substance : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
  
Method : Photodegradation rate calculated by AOPWIN ver. 1.91 based on the methods of Atkinson.  
Remark : 50% degradation after 223.7 hrs or 18.64 days based on a 12-hour day. The computer program AOPWIN (atmospheric oxidation program for Microsoft Windows) (EPI Suite<sup>TM</sup>, 2000) calculates a chemical half-life for a 12-hour day (the 12-hour day half-life value normalizes degradation to a standard day light period during which hydroxyl radicals needed for degradation are generated), based on an OH- reaction rate constant and a defined OH- concentration. EPI Suite<sup>TM</sup> is used and advocated by the US EPA for chemical property estimation.  
Test substance : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
This robust summary has a reliability rating of 2 because the data are calculated.  
Flag : Critical study for SIDS endpoint  
11.05.2006 (4)

#### 3.1.2 STABILITY IN WATER

Type : abiotic  
t1/2 pH4 : at °C  
t1/2 pH7 : 2.7 year at 25 °C  
t1/2 pH9 : at °C  
Deg. product :  
Method : other (calculated)  
Year :  
GLP :  
Test substance : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
  
Method : Hydrolysis rate calculated by HYDROWIN ver. 1.67 based on work for EPA by T. Mill et al.  
Remark : EPI Suite<sup>TM</sup> is used and advocated by the US EPA for chemical property estimation.  
Test substance : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
Reliability : (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are calculated.  
Flag : Critical study for SIDS endpoint  
11.05.2006 (4)

### 3. Environmental Fate and Pathways

Id 131-11-3  
Date 13.12.2006

#### 3.1.3 STABILITY IN SOIL

#### 3.2.1 MONITORING DATA

#### 3.2.2 FIELD STUDIES

#### 3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

#### 3.3.2 DISTRIBUTION

**Media** : air - biota - sediment(s) - soil - water  
**Method** : Calculation according Mackay, Level I  
**Year** :

**Remark** : Physicochemical data used in the calculation:

Parameter	Value w/ Units
-----------	----------------

Molecular Weight	194.19
Temperature	25° C
Log Kow	1.61
Water Solubility	5220 g/m3
Vapor Pressure	0.263 Pa
Melting Point	5.5°C

**Result** : Using the Mackay Level I calculation, the following distribution is predicted for 1,2-Benzenedicarboxylic acid, dimethyl ester:

% Distribution	Compartment
0.2	Air
96.2	Water
3.5	Soil
0.1	Sediment
0.0	Suspended Sediment
0.0	Biota

**Test substance** : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Reliability** : (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are calculated.

**Flag** : Critical study for SIDS endpoint  
14.04.2006

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**Media** : air - biota - sediment(s) - soil - water  
**Method** : Calculation according Mackay, Level III  
**Year** :

**Remark** : Physicochemical data used in the calculation:

Parameter	Value w/ Units
-----------	----------------

Molecular Weight	194.19
Temperature	25° C
Log Kow	1.61
Water Solubility	5220 g/m3

### 3. Environmental Fate and Pathways

Id 131-11-3  
Date 13.12.2006

Vapor Pressure 0.263 Pa  
Melting Point 5.5°C

Emissions rates used in the calculation:

Compartment	Rate (kg/hr)
Air	1000
Water	1000
Soil	1000

Half-lives used in the calculation:

Compartment	Half-life (hr)
Air	447.4a
Water	120b
Soil	420c
Sediment	420c

a - as calculated using AOPWIN version 1.91, a subroutine of the computer program EPI Suite™ version 3.12 and normalized to a 24 hour day [Environmental Protection Agency (EPA) (2000). EPI Suite™, Estimation Program Interface Suite, v3.12. U.S. EPA, Washington, DC, USA.]

b - based on biodegradation data from Sugatt, R.H. et al, 1983 Shake Flask Biodegradation of 14 Commercial Phthalate Esters. Syracuse Research Corporation, Syracuse, NY. SRC# L1543-05. Performed for Chemical Manufacturers Association.

Boethling R (2000). HPVC-Screening Tool: Using Ready and Inherent Biodegradability Data to Derive Input Data for the EQC Model, Appendix 10 in Environment Canada, Environmental Categorization for Persistence Bioaccumulation and Inherent Toxicity of Substances on the Domestic Substance List Using QSARs, Results of an international workshop hosted by Chemicals Evaluation Division of Environment Canada, Nov. 11-12, 1999, in Philadelphia, PA, USA.

c - based on Boethling, R. recommendation that half-lives of 3 to 4 times longer than surface water should be used for soil and sediment.

#### Result

: Using the Mackay Level III calculation, the following distribution is predicted for 1,2-Benzenedicarboxylic acid, dimethyl ester:

Compartment	% Distribution
Air	2.6
Water	19.6
Soil	77.8
Sediment	0.0

#### Test substance Reliability

: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
: (2) valid with restrictions  
This robust summary has a reliability rating of 2 because the data are calculated.

Flag  
11.05.2006

: Critical study for SIDS endpoint

(6)

### 3.4 MODE OF DEGRADATION IN ACTUAL USE

### 3. Environmental Fate and Pathways

Id 131-11-3

Date 13.12.2006

#### 3.5 BIODEGRADATION

Type	: aerobic
Inoculum	: other: Adapted domestic sewage and soil
Concentration	: 20 mg/l related to Test substance related to
Contact time	: 28 day(s)
Degradation	: = 85.9 (±) % after 28 day(s)
Result	:
Deg. product	:
Method	: other
Year	:
GLP	: yes
Test substance	: other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester
Method	: Method/Guideline - USEPA 1982, CO2 Evolution, Shake Flask (modified Gledhill). Inoculum - Domestic sewage and soil. Kinetics - Not Reported Degradation Products - Not Reported Analytical Monitoring - Yes
Result	: Concentration - Nominal test concentration = 20 mg/L for test substance and glucose.  Units - % biodegradation Result - >99% primary biodegradation and 85.9% (s.d. +/-12.2%) ultimate biodegradation.  Primary degradation is expressed as the loss of test substance based on analytical measurements of parent test substance. Ultimate biodegradation is expressed as the percentage of ThCO2 (based on test substance) evolved in each flask.
Test condition	: Test Conditions - Inoculum was aged for 2 weeks prior to test initiation. The test chemical was added to flasks containing medium and inoculum. The flask were incubated and shaken in the dark for 28 days. Three replicates for CO2 evaluation and 4 replicates for primary degradation were tested. The CO2 production was captured in barium hydroxide solution. Primary biodegradation was determined at the beginning, middle and end by GC FID of entire contents of one replicate. A glucose and blank were also tested. 2L Erlenmeyer flasks were used as test vessels. The pH at initiation was 7.0 to 7.2. Test flasks were shaken at a rate of 120 rpm at 22 +/- 2 deg C.
Test substance	: Dimethyl phthalate (CAS# 131-11-3) (1,2,-benzenedicarboxylic acid, dimethyl ester) Synonym: DMP No information on purity, but DMP was analytically confirmed to be within commercial specifications.
Conclusion	: The substance can biodegrad to a high extent using an acclimated population of microorganisms obtained from a sewage treatment system and soil.
Reliability	: (1) valid without restriction This summary is rated a "1" because it followed a USEPA standard guideline, which describes a procedure specifically designed to evaluate biodegradation under acclimated conditions, and the results were reviewed for reliability and assessed as valid.
Flag	: Critical study for SIDS endpoint
26.04.2006	

(14) (15)

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### 3. Environmental Fate and Pathways

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**3.6 BOD5, COD OR BOD5/COD RATIO**

**3.7 BIOACCUMULATION**

**3.8 ADDITIONAL REMARKS**



## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	: flow through												
Species	: Oncorhynchus mykiss (Fish, fresh water)												
Exposure period	: 96 hour(s)												
Unit	: mg/l												
LC50	: = 56 measured/nominal												
Limit test	:												
Analytical monitoring	: yes												
Method	: other												
Year	: 1975												
GLP	: yes												
Test substance	: other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester												
Method	: Method/Guideline - U.S. EPA, (660/3-75-009) Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians. 1975.  Statistical methods - Moving average angle, Probit or Bionomial concentration.												
Result	: 96 hr LC50 = 56.0 mg/L (95% CI = 38.0 to 83.0 mg/L) Mean measured values were used in the LC50 calculation.  Nominal test concentrations: control, 6.2, 12.0, 25.0, 50.0, and 100.0 mg/L. Mean measured test concentrations: <0.036, 6.1, 10.0, 19.0, 38.0, and 83.0 mg/L.  Analytical samples were taken at time zero and on a composite of replicates at study termination. Measured values dropped slightly during the exposure period.  % Mortality results at 96 hrs per replicate for control and treatment levels: Conc. (mg/L) Rep1/Rep2 <table><tr><td>Control</td><td>0 / 0</td></tr><tr><td>6.1</td><td>0 / 0</td></tr><tr><td>10.0</td><td>0 / 0</td></tr><tr><td>19.0</td><td>10 / 0</td></tr><tr><td>38.0</td><td>0 / 0</td></tr><tr><td>83.0</td><td>100 / 100</td></tr></table>	Control	0 / 0	6.1	0 / 0	10.0	0 / 0	19.0	10 / 0	38.0	0 / 0	83.0	100 / 100
Control	0 / 0												
6.1	0 / 0												
10.0	0 / 0												
19.0	10 / 0												
38.0	0 / 0												
83.0	100 / 100												
Test condition	: Test treatments were prepared by using a proportional diluter modified to enhance mixing of phthalates. The dilution water was Wareham Mass. town water (untreated and unchlorinated). A concentrated stock solution was prepared and combined with dilution water prior to pumping into the diluter. The diluter delivered a series of stock dilutions to the test vessels. Test chambers were glass tanks containing 15L of solution. The diluter maintained a water turnover rate of 5 to 8 tank volumes per day. Two replicates of ten organisms were tested per treatment and control. Analytical method was Gas Liquid Chromatography (GLC) with electron capture detection.  Fish mean length = 45 mm and mean wet weight = 0.76 g. Test temperature = 12 +/- 1 Deg C. The pH ranged from 6.7 to 7.4. The mean dissolved oxygen ranged from 8.2 to 9.0 mg/L. Ranges of total hardness and alkalinity as CaCO3 of the dilution water were 20 to 26 mg/L and 14 to 22 mg/L, respectively.												
Test substance	: Fish were obtained from a Montana supplier. Dimethyl phthalate (CAS# 131-11-3) (1,2-benzenedicarboxylic acid, dimethyl ester)												

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**Conclusion** : Synonym: DMP  
Purity: 100% active ingredient  
: Test substance is toxic to fish below its water solubility level.  
Data selected based upon routine species, measured data and  
representative value, as compared with those found in reference  
document, Staples et al. (1997).  
**Reliability** : (1) valid without restriction  
**Flag** : Critical study for SIDS endpoint  
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### 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

**Type** : static  
**Species** : Daphnia magna (Crustacea)  
**Exposure period** : 48 hour(s)  
**Unit** : mg/l  
**EC50** : = 45.9 measured/nominal  
**Analytical monitoring** : yes  
**Method** : other  
**Year** : 1975  
**GLP** : yes  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Method** : Method/Guideline - U.S. EPA, (660/3-75-009) Methods for Acute Toxicity  
Tests with Fish, Macroinvertebrates, and Amphibians. 1975.

**Result** : Statistical methods - Moving average angle, Probit or Bionomial  
Concentration.  
: 48 hr EC50 = 52.0 mg/L (based upon time zero analytical samples;  
confidence intervals were not reported). Value was recalculated as 45.9  
mg/L as per U.S. EPA current practices using mean of measured initiation  
and termination samples as reported in Staples et al. (1997).

Mean measured values were used in the final EC50 calculation.

Nominal test concentrations: control, 39, 66, 110, 180, and 300 mg/L.  
Mean measured test concentrations of time 0 and 48 hr values: <0.007,  
23.5, 38, 62.5, 132, and 225 mg/L.

Analytical samples taken at time zero and on a composite of replicates at  
termination. Measured values declined 33 to 62% during study exposure  
from all test solutions during the test.

% Immobility results at 48 hrs per replicate for control and treatment levels:  
Conc. (mg/L) Rep1/Rep2/Rep3

Control	0 / 0 / 0
23.5	0 / 0 / 40
38	40 / 20 / 20
62.5	80 / 80 / 60
132	100 / 100 / 100
225	100 / 100 / 100

**Test condition** : Test treatments were prepared by mixing the test substance and dilution  
water (fortified well water) in a Polytron homogenizer for 30 minutes. The  
stock solution was prepared at the highest treatment concentration.  
Dilutions of the stock were prepared for each treatment level. Three  
replicates of five organisms were tested per treatment. Test vessels were  
250 ml beakers with 200 ml of test solution. Analytical method was Gas  
Liquid Chromatography (GLC).

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Test temperature = 22.5 +/- 0.5 Deg C. The pH was 8.5 at initiation and ranged from 7.9 to 8.3 on Day 2. Dissolved oxygen ranged from 7.8 to 8.6 at initiation and 6.0 to 8.2 on Day 2. The range of total hardness of the dilution water was 150 to 170 mg/L. Daphnia were <24 hours old and obtained from in-house stock.

**Test substance** : Dimethyl phthalate (CAS# 131-11-3)  
(1,2-benzenedicarboxylic acid, dimethyl ester)  
Synonym: DMP  
Purity: unstated, but believed to be 100% active ingredient because the test material came from the same source as in the rainbow trout acute study.

**Conclusion** : Test substance is toxic to Daphnia below its water solubility level. Data selected based upon routine species, measured data and representative value, as compared with those found in reference document, Staples et al. (1997).

**Reliability** : (2) valid with restrictions  
Some Daphnids were trapped at the surface in all exposure concentrations.

**Flag** : Critical study for SIDS endpoint  
26.04.2006 (10) (13)

### 4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

**Species** : Selenastrum capricornutum (Algae)  
**Endpoint** :  
**Exposure period** : 6 day(s)  
**Unit** : mg/l  
**EC50** : = 142 measured/nominal  
**Limit test** :  
**Analytical monitoring** : yes  
**Method** : other  
**Year** : 1978  
**GLP** : yes  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Method** : Method/Guideline - EPA 600/9-78-018, Printz Algal Assay Bottle Test. 1978.  
Statistical methods - Moving average angle, Probit or Bionomial  
Test type - Static

**Result** : 144 hr (6 day) EC50 = 145.6 mg/L (95% CI = 95.4 to 240.2; based upon time zero analytical samples). Value was recalculated as 142 mg/L as per U.S. EPA current practices using mean of measured initiation and termination samples as reported in Staples et al. (1997).

Mean measured values were used in the final EC50 calculation.

Nominal test concentrations: control, 62.5, 125, 250, 500, and 1000 mg/L.  
Mean measured test concentrations of time 0 and 144 hr values: not detected, 64.7, 133.0, 292.6, 597.7, and 1329.6 mg/L (detection limit was 0.1 mg/L).

Analytical samples taken at time zero and on a composite of replicates at termination. Lowest two concentrations showed stimulatory effect as compared to the control. In-vivo chlorophyll a, measured until less than 5% change. Both cell number and in-vivo chlorophyll a, measured at termination. Control chlorophyll a or cell counts were not reported.

Chlorophyll a percent change relative to control on sampling days and cell number on day 6 results per treatment level:

Conc. Chlorophyll a percent change from control  
(mg/L) Day 3 Day 4 Day 5 Day 6 Cell # Day 6

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	64.7	0	+23	+22	+23	-22
	133.0	-23	+32	+36	+27	-34
	292.6	-83	-84	-86	-83	-93
	597.7	-95	-98	-99	-100	-100
	1329.6	-99	-100	-100	-100	-100
<b>Test condition</b>	: Test substance was added to Algal Growth Medium equal to the highest test concentration (1000 mg/L) and stirred for one hour and settled for one-half hour. Fifty percent (50%) dilutions were made of this stock solution using algal growth media (dilution water and control) and tested. Initial algal concentration was 2.0 E4 cells/ml. Replicate number was not cited.					
<b>Test substance</b>	: Lighting = 4,300 lux, Test temperature = 24+/-1 Deg C. The pH was 7.0 at initiation and ranged from 7.6 to 8.3 on day 6. Algal culture stock was obtained from University of Texas at Austin, TX. Dimethyl phthalate (CAS# 131-11-3) (1,2,-benzenedicarboxylic acid, dimethyl ester) Synonym: DMP Purity: unstated, but believed to be 100% active ingredient as was provided in the rainbow trout study.					
<b>Conclusion</b>	: Test substance is toxic to algae below its water solubility level. Data selected based upon routine species, measured data and representative value, as compared with those found in reference document, Staples et al. (1997).					
<b>Reliability Flag</b>	: (2) valid with restrictions Critical study for SIDS endpoint					
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### 4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

#### 4.5.1 CHRONIC TOXICITY TO FISH

<b>Species</b>	: Oncorhynchus mykiss (Fish, fresh water)
<b>Endpoint</b>	: other: Early Life Stage Toxicity Test
<b>Exposure period</b>	: 60 day(s)
<b>Unit</b>	: mg/l
<b>NOEC</b>	: = 11 measured/nominal
<b>LOEC</b>	: = 24 measured/nominal
<b>Analytical monitoring</b>	: yes
<b>Method</b>	: other
<b>Year</b>	:
<b>GLP</b>	: yes
<b>Test substance</b>	: other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester
<b>Method</b>	: Testing procedures followed the US Environmental Protection Agency, Toxic Substance Control Act (EPA-TSCA) 40 CFR, Part 797.1600 as modified in Testing Consent Agreement 40 CFR, Part 799 (1989), and the American Society for Testing and Materials (ASTM) Standard Guide for Conducting Early Life-Stage Toxicity Tests with Fishes (1990).
<b>Result</b>	: Fry survival and growth (length and weight) were evaluated as the biological endpoints. Dimethyl phthalate ester showed effects on survival and growth. The NOEC was reported as 11 mg/L; the LOEC was reported as 24 mg/L; and the MATC was reported as 16 mg/L. These concentrations are below the water solubility of dimethyl phthalate, which is reported as 4200 mg/L (Staples et al., 1997).
<b>Test condition</b>	: The study used a flow-through test system.
<b>Test substance</b>	: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester
<b>Conclusion</b>	: The chronic fish (Oncorhynchus mykiss) toxicity (early life-stage) data

- reported for dimethyl phthalate are consistent with the data for lower molecular weight phthalate esters as summarized by Rhodes et al. (1995). These data clearly showed that lower molecular weight phthalate esters, including dimethyl phthalate, produce chronic toxicity to a fish at levels below their maximum attainable water solubility.
- Reliability** : (1) valid without restriction  
This study is rated a "1" because it followed an accepted test guideline, used appropriate testing procedures, and applied GLP. The study procedure and results were accepted in a peer reviewed journal. Additionally, the data are consistent with known toxicological properties of similar lower molecular weight phthalate ester substances.
- Flag** : Critical study for SIDS endpoint  
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## 4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

- Species** : Daphnia magna (Crustacea)  
**Endpoint** : other: survival  
**Exposure period** : 21 day(s)  
**Unit** : mg/l  
**NOEC** : = 9.6  
**LOEC** : = 23  
**Analytical monitoring** : yes  
**Method** : other  
**Year** :  
**GLP** : no data  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester
- Method** : The test method followed a procedure developed at the testing lab, Springborn Laboratories, and generally followed the Daphnid chronic testing procedure described in OECD guideline 202 (1984).
- Result** : Five exposure concentrations were used in the study as follows with standard deviation in parenthesis:  
 54 (13); 23 (3); 9.6 (2.1); 5.7 (1.2); and 1.9 (0.6)  
 Survival was significantly different ( $p = 0.05$ ) than the control in the two highest concentrations. Reproduction was not significantly different from the control in any exposure concentration. Therefore the NOEC and LOEC are based on survival, which was the more sensitive endpoint.
- LOEC = 23 mg/L  
 NOEC = 9.6 mg/L  
 MATC = 14.9 mg/L
- | mg/L    | Po %<br>Survival<br>Day 21 | Mean F1<br>Survival<br>Day 21 |
|---------|----------------------------|-------------------------------|
| Control | 89 (sd=2)                  | 116 (sd=17)                   |
| 54      | 69 (sd=5)                  | 145 (sd=8)                    |
| 23      | 54 (sd=24)                 | 150 (sd=31)                   |
| 9.6     | 85 (sd=0)                  | 136 (sd=26)                   |
| 5.7     | 88 (sd=3)                  | 132 (sd=22)                   |
| 1.9     | 86 (sd=2)                  | 138 (sd=37)                   |
- Test condition** : The exposure systems used modified proportional diluters with a 0.5 dilution factor. Materials containing plasticizers were not used in the test systems and no cosolvents were used to prepare stock exposure solutions. A stock exposure solution was prepared daily by mixing vigorously and pumping the solutions to the diluter. The stock solution was prepared at the highest concentration tested, which is well below its maximum water solubility.

The dilution water used for the study and culturing was well water fortified with salts to increase the hardness to 150 to 180 mg/L as CaCO<sub>3</sub>. Alkalinity ranged from 100 to 130 mg/L CaCO<sub>3</sub>, pH ranged from 7.9 to 8.3, and temperature was 21 +/- 2 deg C. Dissolved oxygen concentration was greater than 60% saturation and specific conductance was 400 to 600 umho/cm.

Five exposure concentrations were used in the study as follows with standard deviation in parenthesis:

54 (13); 23 (3); 9.6 (2.1); 5.7 (1.2); and 1.9 (0.6)

Survival and reproduction were assessed every weekday from day 7 to day 21. Offspring were counted and removed on sampling days. Food was added to test vessels three times a day on weekdays and 2 times a day on weekends and holidays.

Dissolved oxygen and temperature were monitored every weekday within one replicate test chamber of each treatment level and control. Total hardness, alkalinity, specific conductance, and pH of test solutions were monitored weekly in one test vessel from each treatment and control.

The diluters delivered 50 ml of test solution to each chamber at a rate equivalent to 4.4 to 5.0 volume replacements daily. Illumination to the test systems was provided by Durotest fluorescent lights located above the test chambers. Sixteen hours of light were provided each day at an intensity of 2 to 4 hectolux (2.94 to 5.88 W m<sup>-2</sup>) at the solution surface.

Test solutions and control water were analyzed for phthalate ester concentration on day 0, 7, 14, and 21. Two of four replicate test chambers were analyzed on sampling days. On each sampling date, two quality assurance samples were prepared and remained with the set of samples through the extraction and analysis procedures.

Each sample was extracted three times with separate 50 ml aliquots of hexane for 2 to 3 minutes. Extracts were combined and volume reduced. Concentrates were stored in 10 ml serum vials at 0 deg C until analyzed. Analysis was by gas chromatography with an electron-capture detector.

**Test substance** : CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester  
**Conclusion** : Dimethyl phthalate produces chronic aquatic toxicity to invertebrates at a concentration below its maximum water solubility.

**Reliability** : (2) valid with restrictions  
This study is rated a "2" because it used appropriate testing procedures. Although a standard test guideline was not used, the procedure was consistent with currently accepted guidelines. The study procedure and results were accepted in a peer reviewed journal. Additionally, the data are consistent with known toxicological properties of similar low molecular weight phthalate ester substances.

**Flag** : Critical study for SIDS endpoint

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#### 4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

#### 4.6.2 TOXICITY TO TERRESTRIAL PLANTS

#### 4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

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### **4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES**

### **4.7 BIOLOGICAL EFFECTS MONITORING**

### **4.8 BIOTRANSFORMATION AND KINETICS**

### **4.9 ADDITIONAL REMARKS**

**5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION****5.1.1 ACUTE ORAL TOXICITY**

**Type** : LD50  
**Value** : = 6900 mg/kg bw  
**Species** : rat  
**Strain** :  
**Sex** : no data  
**Number of animals** : 40  
**Vehicle** : other: Undiluted test material administered  
**Doses** :  
**Method** : other  
**Year** : 1948  
**GLP** : no  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Result** : There were no remarkable findings noted during the post-treatment observation period.

**Test condition** : Rats were fasted for 18 hours prior to receiving the test compound. The animals were observed for six days following dosing and all deaths were recorded. The dose levels of dimethyl phthalate used in this study were not specified. The material was administered in graded doses so that a dose-mortality curve could be determined. The LD50 was estimated from this dose-mortality curve.

**Test substance** : 1,2-benzenedicarboxylic acid, dimethyl ester (dimethyl phthalate)  
CAS #: 131-11-3

**Conclusion** : Under the conditions of this study, dimethyl phthalate has a low order of acute oral toxicity in rats.

**Reliability** : (2) valid with restrictions  
Insufficient data on the actual doses used.

**Flag** : Critical study for SIDS endpoint  
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**5.1.2 ACUTE INHALATION TOXICITY**

02.01.2001

**5.1.3 ACUTE DERMAL TOXICITY****5.1.4 ACUTE TOXICITY, OTHER ROUTES****5.2.1 SKIN IRRITATION****5.2.2 EYE IRRITATION**



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### 5.3 SENSITIZATION

### 5.4 REPEATED DOSE TOXICITY

Type	:	
Species	:	rabbit
Sex	:	no data
Strain	:	
Route of admin.	:	dermal
Exposure period	:	90 days
Frequency of treatm.	:	Once Daily
Post exposure period	:	Not Specified
Doses	:	Up to 4 ml/kg (>4 g/kg)
Control group	:	no data specified
Method	:	other
Year	:	1948
GLP	:	no
Test substance	:	other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester
Result	:	Systemic effects observed at the highest dose level (4 ml/kg).  Signs of toxicity included nephritis at the two higher dose levels; pulmonary edema and slight kidney damage. No evidence of dermatitis was observed.
Test condition	:	Limited data are available on the test conditions. Tissues collected from rabbits receiving the test material for 90 days were subjected to histopathological evaluations. Approximately 7000 individual tissues were examined.
Test substance	:	1,2-benzenedicarboxylic acid, dimethyl ester (dimethyl phthalate) CAS #: 131-11-3
Conclusion	:	Based on the results of this study, it was concluded that the test material was safe for its recommended use.
Reliability	:	(2) valid with restrictions Limited detail regarding the experimental design and dose selection.
Flag	:	Critical study for SIDS endpoint
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### 5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	Salmonella typhimurium TA98; TA100; TA1535; TA1537
Test concentration	:	0, 33, 100, 333, 1,000, 2166, 3000, 3333, 5000, 6666 mg/plate
Cycotoxic concentr.	:	6666 mg/plate
Metabolic activation	:	with and without
Result	:	negative
Method	:	OECD Guide-line 471
Year	:	1985
GLP	:	no data
Test substance	:	other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester
Method	:	Metabolic activation: With and without S9 (metabolic activation enzymes and cofactors from Aroclor 1254-induced male Sprague-Dawley rat or Syrian hamster liver);

Statistical Methods: A positive response was defined as a reproducible, dose-related increase in histidine-independent colonies (revertants) in any one strain/activation combination. An equivocal response is defined as an

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	<p>increase in revertants which is not dose-related, not reproducible or is not of sufficient magnitude to support mutagenicity. A negative response is obtained when there is no increase in revertant colonies.</p>
<b>Result</b>	: Dimethyl phthalate was negative in all strains. The high dose of DMP (6666 mg/plate) was toxic to the bacteria.
<b>Test condition</b>	: Dimethyl phthalate was incubated in the tester strains either in buffer or S9 mix for 20 minutes at 37°C. Top agar supplemented with l-histidine and d-biotin was added, and the contents of the tubes were mixed and poured onto the surfaces of minimal glucose agar plates. Histidine-independent mutant colonies arising on these plates were counted following incubation for 2 days at 37°C. Three replicates were used for each dose. Positive controls were as follows: Sodium azide (TA 1535, TA 100), 4-nitro-o-phenylenediamine (TA 98), 9-aminoacridine (TA 1537). Concurrent solvent and positive controls were included in all experiments. A preliminary range-finding study was used to determine the high dose level. This study was conducted with TA 100 in the presence and absence of S-9. A repeat assay was performed in order to verify the data produced in the initial assay.
<b>Test substance</b>	: 1,2-benzenedicarboxylic acid, dimethyl ester (dimethyl phthalate) CAS #: 131-11-3
<b>Conclusion</b>	: No mutagenic activity was observed with dimethyl phthalate in Salmonella strains TA 98, TA 100, TA 1535 and TA 1537.
<b>Reliability</b>	: (1) valid without restriction NTP-sponsored study.
<b>Flag</b> 05.07.2006	: Critical study for SIDS endpoint (7)
<b>Type</b>	: Chromosomal aberration test
<b>System of testing</b>	: Chinese Hamster Ovary (CHO) cells
<b>Test concentration</b>	: 10.5 hr incubation: 150, 498 and 1500 mg/ml 12.0 hr incubation: 498, 1500 and 4980 mg/ml 20.5 hour incubation: 3060, 4080 and 5100 mg/ml
<b>Cycotoxic concentr.</b>	:
<b>Metabolic activation</b>	: with and without
<b>Result</b>	: negative
<b>Method</b>	: OECD Guide-line 473
<b>Year</b>	: 1987
<b>GLP</b>	: yes
<b>Test substance</b>	: other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester
<b>Method</b>	: With and without S9 (metabolic activation enzymes and cofactors from Aroclor 1254-induced male Sprague-Dawley rats).
	<p>Statistical tests were performed on both the dose response curve and individual dose points. A statistically significant (<math>P &lt; 0.05</math>) difference for one dose point and a significant trend (<math>P &lt; 0.015</math>) were considered weak evidence of a positive response; significant differences for two or more doses indicate the trial is positive.</p>
<b>Result</b>	: Negative. No induction of chromosomal aberrations was observed in CHO cells in the presence or absence of S9.
<b>Test condition</b>	: In the assay without S9, cells were incubated in McCoys 5A medium for 8.5 hours. Colcemid was added and incubation continued for 2 hours. Cells treated with S9 were treated with dimethyl phthalate for 2 hours, after which the treatment medium was removed and cells were then incubated for 10 hours in fresh medium. Colcemid was added during the final 2 hours of the incubation. Cells were selected for scoring based on good morphology and karyotype. Slides were scored blind and were read by the same person. DMSO was used as the solvent control at all incubation time points. Mitomycin-C was used as the positive control at 10.5 hours. Cyclophosphamide was used as the positive control at both 12.0 and 20.5 hours incubations. Two trials were conducted with S9, one using the standard 12 hour incubation while the second used a 20.5 hour incubation

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to ensure that CHO cells were exposed to DMP for at least one complete cell cycle.

**Test substance** : 1,2-benzenedicarboxylic acid, dimethyl ester (dimethyl phthalate)  
CAS #: 131-11-3

**Conclusion** : Under conditions of this study, dimethyl phthalate was inactive in the chromosome aberration assay at doses up to 5100 mg/ml.

**Reliability** : (1) valid without restriction  
Valid without restrictions

**Flag** : Critical study for SIDS endpoint  
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### 5.6 GENETIC TOXICITY 'IN VIVO'

### 5.7 CARCINOGENICITY

#### 5.8.1 TOXICITY TO FERTILITY

#### 5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Species** : rat  
**Sex** : female  
**Strain** : Sprague-Dawley  
**Route of admin.** : oral feed  
**Exposure period** : Gestation days 6-15  
**Frequency of treatm.** : Daily  
**Duration of test** :  
**Doses** : 0.0, 0.25, 1.0 or 5.0% (0, 0.20, 0.84, and 3.57 g/kg/day).  
**Control group** : yes  
**NOAEL maternal tox.** : = 840 mg/kg bw  
**NOAEL teratogen.** : > 3570 - mg/kg bw  
**Method** : OECD Guide-line 414 "Teratogenicity"  
**Year** : 1993  
**GLP** : yes  
**Test substance** : other TS: CAS #131-11-3; 1,2-Benzenedicarboxylic acid, dimethyl ester

**Method** : Statistical methods: ANOVA; Williams' and Dunnett's Multiple Comparison Test, Fisher's exact probability test

**Result** : The actual doses received were 0.20, 0.84 and 3.57 g/kg/day based on maternal body weights and food consumption. No dams died during gestation. Pregnancy rates were 89-93% for all treatment groups. Food consumption and body weight decreases were observed in animals in the 5.0% treatment groups. Relative kidney weight was increased in the high dose group. No histopathologic effects on the kidneys were observed in any of the treatment groups. In addition, there were no effects on the number of implantation sites, or percent resorptions.

No effects on mean fetal body weight, viability, sex ration, or growth and development.

**Test condition** : After a 7 day quarantine period, breeding pairs were cohabited overnight. Gestation day 0 was determined the morning that vaginal sperm was found. Initial body weights of females were between 207- 273 grams. On gestation day 0, animals were randomly assigned to treatment groups consisting of 25-32 animals. Animals were weighed on the morning of gestation day 0, 3, 6, 9, 12, 15, 18 and 20. In addition, animals were observed daily for signs of toxicity. Animals were observed daily for overt

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signs of toxicity. On GD 20, animals were sacrificed and maternal body, liver, kidneys, and intact uterus were weighed. Fetuses were weighed, examined for external and visceral abnormalities.

**Test substance** : 1,2-benzenedicarboxylic acid, dimethyl ester (dimethyl phthalate)  
CAS #: 131-11-3

**Conclusion** : Under the conditions of this study, DMP was not a selective developmental toxicant. DMP exposure was associated with maternal effects at the high dose level.

**Reliability** : (1) valid without restriction  
Comparable to guideline study.

**Flag** : Critical study for SIDS endpoint  
05.07.2006 (5)

### 5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

### 5.9 SPECIFIC INVESTIGATIONS

### 5.10 EXPOSURE EXPERIENCE

### 5.11 ADDITIONAL REMARKS

**6.1 ANALYTICAL METHODS**

**6.2 DETECTION AND IDENTIFICATION**

**7.1 FUNCTION**

**7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED**

**7.3 ORGANISMS TO BE PROTECTED**

**7.4 USER**

**7.5 RESISTANCE**

**8.1 METHODS HANDLING AND STORING**

**8.2 FIRE GUIDANCE**

**8.3 EMERGENCY MEASURES**

**8.4 POSSIB. OF RENDERING SUBST. HARMLESS**

**8.5 WASTE MANAGEMENT**

**8.6 SIDE-EFFECTS DETECTION**

**8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER**

**8.8 REACTIVITY TOWARDS CONTAINER MATERIAL**

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### 10.1 END POINT SUMMARY

### 10.2 HAZARD SUMMARY

**Memo** : This chemical is part of the Low Molecular Weight Phthalate Esters subcategory. Data from other chemicals in this subcategory can be used to assess the potential hazards of all category members.

**Remark** : There is a large amount of data for the physicochemical properties of dimethyl and diethyl phthalate. Computer models were also used to estimate these properties for comparison with measured values and additionally were used to predict environmental distribution.

A complete health effects SIDS data set is available for diethyl phthalate, and for dimethyl phthalate with the exception of adequate reproductive data. Both DMP and DEP show minimal acute toxicity, are not genotoxic, exhibit some liver and kidney effects at high doses, and are negative for developmental effects. Although adequate reproductive data are not available for DMP, data on DEP indicate that this material will not cause reproductive effects. This is further supported by data showing that neither DEP nor DMP had effects on male reproductive development. The lack of developmental effects observed with DMP, coupled with chronic toxicity studies showing no effects on reproductive organs, negates the need to conduct a reproductive study for DMP.

There are numerous published acute aquatic toxicity studies in a variety of species of fish, daphnia and algae for DMP and DEP. DMP and DEP are slightly soluble in aqueous systems. Acute effects on aquatic species are seen in the 10 to 100 ppm range.  
Chapters 2,3,4 & 5

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### 10.3 RISK ASSESSMENT